



Council of the
European Union

Brussels, 15 March 2021
(OR. en)

7043/21
ADD 1

COMPET 182
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COVER NOTE

From: Secretary-General of the European Commission, signed by Ms Martine DEPREZ, Director

date of receipt: 12 March 2021

To: Mr Jeppe TRANHOLM-MIKKELSEN, Secretary-General of the Council of the European Union

No. Cion doc.: [...] (2021) XXX draft - D 071310 ANNEX

Subject: ANNEX to the COMMISSION REGULATION (EU) .../... amending Annex XVII to Regulation (EC) No 1907/2006 of the European Parliament and of the Council as regards perfluorocarboxylic acids containing 9 to 14 carbon atoms in the chain (C9-C14 PFCAs), their salts and C9-C14 PFCA-related substances

Delegations will find attached document [...] (2021) XXX draft - D 071310 ANNEX.

Encl.: [...] (2021) XXX draft - D 071310 ANNEX



Brussels, **XXX**
D071310/03
[...](2021) **XXX** draft

ANNEX

ANNEX

to the

COMMISSION REGULATION (EU) .../...

amending Annex XVII to Regulation (EC) No 1907/2006 of the European Parliament and of the Council as regards perfluorocarboxylic acids containing 9 to 14 carbon atoms in the chain (C9-C14 PFCAs), their salts and C9-C14 PFCA-related substances

ANNEX

In Annex XVII, entry 68 is replaced by the following:

<p>‘XX. Linear and branched perfluorocarboxylic acids of the formula $C_nF_{2n+1}-C(=O)OH$ where $n=8, 9, 10, 11, 12,$ or 13 (C9-C14 PFCAs), including their salts, and any combinations thereof;</p> <p>Any C9-C14 PFCA-related substance having a perfluoro group with the formula $C_nF_{2n+1}-$ directly attached to another carbon atom, where $n=8, 9, 10, 11, 12,$ or $13,$ including their salts and any combinations thereof;</p> <p>Any C9-C14 PFCA-related substance having a perfluoro group with the formula $C_nF_{2n+1}-$ that it is not directly attached to another carbon atom, where $n= 9, 10, 11, 12, 13$ or 14 as one of the structural elements, including their salts and any combinations thereof.</p> <p>The following substances are excluded from this designation</p> <ul style="list-style-type: none">• $C_nF_{2n+1}-X,$ where $X= F, Cl,$ or Br where $n=9, 10, 11, 12, 13$ or $14,$ including any combinations thereof;• $C_nF_{2n+1}-C(=O)OX'$ where $n>13$ and X'=any group, including salts. <hr/>	<ol style="list-style-type: none">1. Shall not be manufactured, or placed on the market as substances on their own from [date-18 months after date of entry into force].2. Shall not, from [date-18 months from entry into force], be used in, or placed on the market in:<ol style="list-style-type: none">(a) another substance, as a constituent;(b) a mixture;(c) an article,except if the concentration in the substance, the mixture, or the article is below 25 ppb for the sum of C9-C14 PFCAs and their salts or 260 ppb for the sum of C9-C14 PFCA-related substances.3. By way of derogation to paragraph 2, the concentration limit shall be 10 ppm for the sum of C9-C14 PFCAs, their salts and C9-C14 PFCA related substances, where they are present in a substance to be used as a transported isolated intermediate, provided that the conditions in points (a) to (f) of Article 18 (4) of this Regulation are met for the manufacturing of fluorochemicals with a perfluoro carbon chain length equal to or shorter than 6 atoms. The Commission shall review this limit no later than [date 24 months after the entry into force].4. Paragraph 2 shall apply from 4 July 2023 to :<ol style="list-style-type: none">(i) textiles for oil- and water-repellency for the protection of workers from dangerous liquids that comprise risks to their health and safety;(ii) the manufacture of polytetrafluoroethylene (PTFE) and polyvinylidene fluoride (PVDF) for the production of :<ul style="list-style-type: none">- high performance, corrosion resistant gas filter membranes, water filter membranes and membranes for medical textiles;- industrial waste heat exchanger equipment;- industrial sealants capable of preventing leakage of volatile
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organic compounds and PM 2.5 particulates

5. By way of derogation to paragraph 2, the use of C9-C14 PFCAs, their salts and C9-C14 PFCA-related substances shall be allowed until 4 July 2025 for

(i) photolithography or etch processes in semiconductor manufacturing;

(ii) photographic coatings applied to films;

(iii) invasive and implantable medical devices;

(iv) fire-fighting foam for liquid fuel vapour suppression and liquid fuel fire (Class B fires) already installed in systems, including both mobile and fixed systems, subject to the following conditions:

- fire-fighting foam that contains or may contain C9-C14 PFCAs, their salts and C9-C14 PFCA-related substances shall not be used for training;
- fire-fighting foam that contains or may contain C9-C14 PFCAs, their salts and C9-C14 PFCA-related substances shall not be used for testing unless all releases are contained;
- from 1 January 2023, uses of fire-fighting foam that contains or may contain C9-C14 PFCAs, their salts and C9-C14 PFCA-related substances shall only be allowed to sites where all releases can be contained;
- fire-fighting foam stockpiles that contain or may contain C9-C14 PFCAs, their salts and C9-C14 PFCA-related substances shall be managed in accordance with Article 5 of Regulation (EU) 2019/1021.

6. Paragraph 2(c) shall not apply to articles placed on the market before [date-18 months after date of entry into force].

7. Paragraph 2 shall not apply to the can coating for pressurised metered-dose inhalers until [date-seven years after the entry into force].

8. Paragraph 2 (c) shall apply from 31 December 2023 to:

- (a) semiconductors on their own;
- (b) semiconductors incorporated in semi-finished and finished electronic equipment.

9. Paragraph 2(c) shall apply from 31 December 2030 to semiconductors used in spare or replacement parts for finished electronic equipment placed on the market before 31 December 2023.

10. Until [date- 36 months after the entry into force of the restriction], the concentration limit referred to in paragraph 2 shall be 2 000 ppb for the sum of C9-C14 PFCAs in fluoroplastics and fluoroelastomers that contain perfluoroalkoxy groups. From [date 36 months after the entry into force of the restriction], the concentration limit shall be 100 ppb for the sum of C9-C14 PFCAs, in fluoroplastics and fluoroelastomers that contain perfluoroalkoxy groups. All emissions of C9-C14 PFCAs during the manufacture and use of fluoroplastics and fluoroelastomers that contain perfluoroalkoxy groups shall be avoided and, if not possible, reduced as far as technically and practically possible. This derogation shall not apply to articles referred to in paragraph 2 (c). The Commission shall review this derogation no later than [36 months after the entry into force of the restriction].

11. The concentration limit referred to in paragraph 2 shall be 1000 ppb for the sum of C9-C14 PFCAs, where these are present in PTFE micro powders produced by ionising irradiation or by thermal degradation, as well as in mixtures and articles for industrial and professional uses containing PTFE micro powders. All emissions of C9-C14 PFCAs during the manufacture and use of PTFE micro powders shall be avoided and, if not possible, reduced as far as technically and practically possible. The Commission shall review this derogation no later than [36 months after the entry into force of the restriction].

	<p>12. For the purposes of this entry, C9-C14 PFCA-related substances are substances that, based on their molecular structure, are considered to have the potential to degrade or be transformed to C9-C14 PFCAs.’</p>
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